

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031

U.S. Patent and Trademark Office U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 5	Confirmation Number	2148
	Application Number	09/966,447
	Filing Date	September 28, 2001
	First Named Inventor	David C. Lentz
	Group Art Unit	3773
	Examiner Name	Ryckman, M. K.
	Attorney Docket Number	CRD0957USNP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
		3,929,992		Seghal, et al.	12-30-1975	
		4,350,160		Kolesov, et al.	09-21-1982	
		4,366,819		Kaster	01-04-1983	
		4,368,736		Kaster	01-18-1983	
		4,624,257		Berggren, et al.	11-25-1986	
		4,722,906		Guire	02-02-1988	
		4,917,090		Berggren, et al.	01-19-1988	
		4,917,091		Berggren, et al.	04-17-1988	
		5,229,172	A	Cahalan, et al.	07-20-1993	
		5,234,160		Lisiecki	08-10-1993	
		5,234,447	A	Kaster, et al.	08-10-1993	
		5,308,641	A	Cahalan, et al.	05-03-1994	
		5,392,747		Williams, et al.	11-04-1992	
		5,415,938	A	Cahalan, et al.	05-16-1995	
		6,153,252		Hossainy	04-19-1999	

Examiner Signature	Date Considered
-----------------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

PTO/SD/08A (08-00)
Approved for use through 10/31/2002. OMB 0851-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 5

Confirmation Number	2148
Application Number	09/966,447
Filing Date	September 28, 2001
First Named Inventor	David C. Lentz
Group Art Unit	3773
Examiner Name	Ryckman, M. K.
Attorney Docket Number	CRD0957USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		AJROLDI, G. et al., "Fluoroelastomers-Dependence of Relaxation Phenomena on Compositions", POLYMER, 30, No. 12, (1989): 2180-2187.	
		BERK, B.C. et al., "Pharmacologic Roles of Heparin and Glucocorticoids to Prevent Restenosis After Coronary Angioplasty", J. Am. Coll. Cardio. Vol. 17, No. 6, pp. 111B-117B (1991)	
		CAMPBELL and CAMPBELL, "Phenotypic Modulation of Smooth Muscle Cells in Primary Culture", (Table of Contents), Chapter 2, Volume 1, pp. 39-52 (1985)	
		CAMPBELL and CAMPBELL "Cell Biology of Smooth Muscle in Culture: Implications for Atherogenesis", Inter. Angio. 6, p. 73 (1987).	
		CHANG, M.W. et al., "Adenovirus-mediated Over-expression of the Cyclin/Cyclin-Dependent Kinase Inhibitor, p21 Inhibits Vascular Smooth Muscle Cell Proliferation and Neointima Formation in the Rat Carotid Artery Model of Balloon Angioplasty", J. Clin. Invest. Vol. 96, pp. 2250-2258 (1995).	
		CLOWES, A.W. et al., "Suppression by Heparin of Smooth Muscle Cell Proliferation in Injured Arteries", Nature, Vol. 265, pp. 625-626 (1977)	
		CLOWES, A.W. et al., "Kinetics of Cellular Proliferation after Arterial Injury", Laboratory Investigation, Vol. 52, No. 6, pp. 611-616 (1985)	
		CLOWES, A.W. et al., "Kinetics of Cellular Proliferation after Arterial Injury IV. Heparin Inhibits Rat Smooth Muscle Mitogenesis and Migration", Circulation Research, Vol. 58, No. 6, pp. 839-845 (1986)	
		CLOWES and SCHWARTZ, "Significance of Quiescent Smooth Muscle Migration in the Injured Rat Carotid Artery", Cir. Res. 56: 139-145 (1985)	
		COLBURN, M.D. et al., "Dose Responsive Suppression of Myointimal Hyperplasia by Dexamethasone", J. Vasc. Surg. Vol. 15, No. 3, pp. 510-518 (1992)	
		CURRIER, J.W. et al., "Colchicine Inhibits Restenosis After Iliac Angioplasty in the Atherosclerotic Rabbit", Supplement II Circulation Vol. 80, No. 4, II-66 (1989)	
		EDELMAN, E., et al. "Pathobiologic Responses to Stenting", American Journal of Cardiology Vol. 91, Issue 7, Suppl. 1 (April 1998) pp. 4E-6E	
		FARB, A. et al., "Vascular Smooth Muscle Cell Cytotoxicity and Sustained Inhibition of Neointimal Formation by Fibroblast Growth Factor 2-Saporin Fusion Protein", Circ. Res. Vol. 80, No. 4, pp. 542-550 (1997)	
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Approved for use through 10/31/2002. OMB 0665-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 5

Confirmation Number	2148
Application Number	09/966,447
Filing Date	September 28, 2001
First Named Inventor	David C. Lentz
Group Art Unit	3773
Examiner Name	Ryckman, M. K.
Attorney Docket Number	CRD0957USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

	FERNIS, G.A. et al., "Inhibition of Neointimal Smooth Muscle Accumulation After Angioplasty by an Antibody to PDGF", Science, Vol. 253, pp. 1129-1132 (1991)	
	FISCHMAN, D., et al. "A Randomized Comparison of Coronary-Stent Placement and Balloon Angioplasty in the Treatment of Coronary Artery Disease", The New England Journal of Medicine, Volume 331:496-501 (1994)	
	FRANKLIN and FAXON S., et al. "Pharmacologic Prevention of Restenosis After Coronary Angioplasty: Review of the Randomized Clinical Trials", Coronary Artery Disease, Vol. 4, No. 3 (March 1993)	
	FUKUYAMA J., et al., "Tranilast Suppresses the Vascular Intimal Hyperplasia After Balloon Injury in Rabbits Fed on a High-Cholesterol Diet", European Journal of Pharmacology 318, pp. 327-332 (1996)	
	GUYTON, J.R. et al., "Inhibition of Rat Arterial Smooth Muscle Cell Proliferation by Heparin", Circulation Research, Vol. 46, No. 5, pp. 625-634 (1980)	
	HANSON, S.R. et al., "Interruption of Acute Platelet-Dependent Thrombosis by the Synthetic Antithrombin D-Phenylalanyl-L-Prolyl-L-Arginyl Chloromethyl Ketone", Roc. Natl. Acad. Sci. USA (5/1988) 85: 3184-3188.	
	HANSSON, G.K., et al., "Interferon- γ Inhibits Arterial Stenosis After Injury" Circulation, Vol. 84, No. 3, pp. 1266-1272 (1991)	
	JONASSON, L. et al., "Cyclosporin A Inhibits Smooth Muscle Proliferation in the Vascular Response to Injury", Proc. Natl. Acad. Sci. USA Vol. 85, pp. 2303-2306, (1988)	
	LANG R., et al. "Effects of Okadaic Acid and ATP γ S on Cell Length and CA $^{2+}$ - Channel Currents Recorded in single Smooth Muscle Cells of the Guinea-Pig Taenia Caeci", Br. J. Pharmacol. 104, p. 331-336 (1991)	
	LIU, M.W. et al., "Trapidil in Preventing Restenosis After Balloon Angioplasty in the Atherosclerotic Rabbit", Circ. Vol. 81, No. 3, pp. 1089-1093 (1990)	
	LUNDERGAN, C.F. et al., "Peptide Inhibition of Myointimal Proliferation by Angiostatin, a Somatostatin Analogue", JACC Vol. 17(Sup. B), No. 6, pp. 132B-136B (1991)	
	MAJESKY, M.W. et al., "Heparin Regulates Smooth Muscle S Phase Entry in the Injured Rat Carotid Artery", Circ. Res. Vol. 61, No. 2, pp. 296-300 (1987)	
	MAK and TOPOL, "Clinical Trials to Prevent Restenosis after Percutaneous Coronary Revascularization", Department of Cardiology, Cleveland Clinical Foundation, Ohio p. 255 (1991)	
	MARX, S.O., et al., "Rapamycin-FKBP Inhibits Cell Cycle Regulators of Proliferation in Vascular Smooth Muscle Cells", Circ. Res., Vol. 76, No. 3, pp. 412-417 (1995)	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22315-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MR/

PTO/SD/08A (08-00)
Approved for use through 10/31/2002. OMB 0861-0001
U.S. Patent and Trademark Office U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 4 of 5	Confirmation Number	2148
	Application Number	09/966,447
	Filing Date	September 28, 2001
	First Named Inventor	David C. Lentz
	Group Art Unit	3773
	Examiner Name	Ryckman, M. K.
	Attorney Docket Number	CRD0957USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		NEMECEK, G.M. et al., "Terbinafine Inhibits the Mitogenic Response to Platelet-Derived Growth Factor <i>in Vitro</i> and Neointimal Proliferation <i>in Vivo</i> ", J. Pharmacol. Exp. Ther. Vol. 248, No. 3, pp.1167-1174 (1989)	
		OKADA, T. et al., Localized Release of Perivascular Heparin Inhibits Intimal Proliferation after Endothelial Injury without Systemic Anticoagulation, Neurosurgery, Vol. 25, No. 6, pp. 892-898 (1989)	
		POMPA, J., et al., "Clinical Trials of Restenosis after Coronary Angioplasty", American Heart Association, Circulation, (1991) 84:1426-1436	
		POWELL, J.S. et al., Inhibitors of Angiotensin-Converting Enzyme Prevent Myointimal Proliferation After Vascular Injury, Science, Vol. 245, pp. 186-188 (1989)	
		SERRUYIS P., et al. "Evaluation of Ketanserin in the Prevention of Restenosis After Percutaneous Transluminal Coronary Angioplasty. A Multicenter Randomized Double-Blind Placebo-Controlled Trial", American Heart Association, Circulation, 88, p. 1588 (1993)	
		SERRUYIS, P., et al. "A Comparison of Balloon-Expandable-Stent Implantation with Balloon Angioplasty in Patients with Coronary Artery Disease", New England Journal of Medicine, Volume 331:489-495 (1994)	
		SERRUYIS, P., et al. "Heparin-Coated Palmaz-Schatz Stents in Human Coronary Arteries: Early Outcome of the Benestent-II Pilot Study", Circulation of the American Heart Association, Volume 93(3) p. 412-422 (1996)	
		SIMONS, M. et al., "Antisense <i>c-myc</i> oligonucleotides inhibit intimal arterial smooth muscle cell accumulation <i>in vivo</i> ", Nature, Vol. 359, pp. 67-70 (1992)	
		SNOW, A.D. et al., "Heparin Modulates the Composition of the Extracellular Matrix Domain Surrounding Arterial Smooth Muscle Cells", Vol. 137, No. 2, pp. 313-330, (1990)	
		SOLLIT, S.J. et al., "Taxol Inhibits Neointimal Smooth Muscle Cell Accumulation after Angioplasty in the Rat", J. Clinical Investigation, Inc. Vol. 95, pp. 1869-1876, (1995)	
		TANAKA, H., et al. "Sustained Activation of Vascular Cells and Leukocytes in the Rabbit Aorta After Balloon Injury", Circulation, Vol. 88, 1788-1803 (1993)	
		TARDIF, J.-C., et al. "Probucol and Multivitamins in the Prevention of Restenosis After Coronary Angioplasty", New England Journal of Medicine, Volume 337:365-372 (1997)	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time should be completed by the appropriate symbol to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MR/

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
to a collection of information unless it displays a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 5 of 5

Confirmation Number	2148
Application Number	09/966,447
Filing Date	September 28, 2001
First Named Inventor	David C. Lentz
Group Art Unit	3773
Examiner Name	Ryckman, M. K.
Attorney Docket Number	CRD0957USNP

TEIRSTEIN, P., et al. "Catheter-Based Radiotherapy to Inhibit Restenosis After Coronary Stenting", *The New England Journal of Medicine*, Volume 336 p. 1697 (June 1997)

WEINBERGER, J. et al., "Intracoronary Irradiation: Dose Response for the Prevention of Restenosis in Swine", *Int. J. Radiation Onc. Biol. Phys. Vol. 36, No. 4, pp. 767-775* (1996)

WILEY and SONS, "Fluoro Carbon Elastomers, Modern Fluoropolymers", *Wiley Series in Polymer Science*, p. 71-90 (1997)

YOKOI H., et al. "Effectiveness of an Antioxidant in Preventing Restenosis After Percutaneous Transluminal Coronary Angioplasty: The Probaluc Angioplasty Restenosis Trial", *JACC Vol. 30, No. 4 p. 855-862* (1997)

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.
DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Examiner Signature	/Melissa Byckman/ (01/30/2010)	Date Considered	
--------------------	--------------------------------	-----------------	--

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MR/